

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark
Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 12 June 1997 (12.06.97)	
International application No. PCT/US96/15596	Applicant's or agent's file reference 15050.4.1
International filing date (day/month/year) 20 September 1996 (20.09.96)	Priority date (day/month/year) 22 September 1995 (22.09.95)
Applicant MUNDSCHENK, David, D.	

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

22 April 1997 (22.04.97)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer F. Gateau Telephone No.: (41-22) 338.83.38
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PCT

WIPO PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 15050.4.1	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US96/15596	International filing date (day/month/year) 20 SEPTEMBER 1996	Priority date (day/month/year) 22 SEPTEMBER 1995
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant PHYLOMED CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of — sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 22 APRIL 1997	Date of completion of this report 07 NOVEMBER 1997
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JOHN PAK <i>IW for</i> Telephone No. (703) 308-1235

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US96/15596

I. Basis of the report

1. This report has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments)*:

- ☒ the international application as originally filed.
- ☒ the description, pages 1-19 , as originally filed.
pages NONE , filed with the demand.
pages NONE , filed with the letter of _____.
pages _____ , filed with the letter of _____.
- ☒ the claims, Nos. 1-20 , as originally filed.
Nos. NONE , as amended under Article 19.
Nos. NONE , filed with the demand.
Nos. NONE , filed with the letter of _____.
Nos. _____ , filed with the letter of _____.
- ☒ the drawings, sheets/fig NONE , as originally filed.
sheets/fig NONE , filed with the demand.
sheets/fig NONE , filed with the letter of _____.
sheets/fig _____ , filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE .
- ☒ the claims, Nos. NONE .
- ☒ the drawings, sheets/fig NONE .

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US96/15596

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

Novelty (N)	Claims <u>9-10, 19-20</u>	YES
	Claims <u>1-8, 11-18</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-20</u>	NO
Industrial Applicability (IA)	Claims <u>1-20</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 9-10 and 19-20 meet the criteria set forth in PCT Article 33(2), because no single prior art reference can be found that explicitly discloses a delivery system comprising an aerosol dispenser containing purified sea water and an anionic surface active agent.

Claims 1-20 meet the criteria set forth in PCT Article 33(4), because the claimed invention finds industrial applicability in the delivery of active chemical agents.

Claims 1-8 and 11-18 lack novelty under PCT Article 33(2) as being anticipated by Jass et al.

Jass et al. explicitly disclose an aerosol dispenser that contains 3% hydrogen peroxide and 0.6% sodium lauryl sulfate (see Example A in columns 7-8, in particular, column 8, lines 48, 54 and 60-68). Consequently, instant claims 1-8 and 11-18 are anticipated by Jass et al.

Claims 1-20 lack an inventive step under PCT Article 33(3) as being obvious over Jass et al.

Jass et al. disclose the aerosol delivery of active agents (see from column 1, line 66 to column 2, line 6; and column 5, line 23 to column 6, line 65). Hydrogen peroxide with surfactant such as sodium lauryl sulfate is disclosed (column 5, line 45; column 6, lines 57-58; Example A at columns 7-8). Carrier system containing sodium lauryl sulfate is disclosed (Table I at columns 7-8).

The only difference between the claimed invention and Jass et al. is that Jass et al. do not expressly disclose the use of purified sea water as the "chemical agent." However, given the status of purified sea water as a well known therapeutic agent (see applicant's admission in description page 3, lines 7-10), its incorporation into Jass' delivery system for myriad active agents would have been well within the skill of the ordinary skilled artisan.

Therefore, the claimed invention, as a whole, would have been obvious to the routineer in the art, and claims 1-20 lack an inventive step under PCT Article 33(3).

----- NEW CITATIONS -----

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US96/15596

VI. Certain documents cited**1. Certain published documents (Rule 70.10)**

<u>Application No. Patent No.</u>	<u>Publication Date (day/month/year)</u>	<u>Filing Date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
US, A, 5,512,278 (MUNDSCHEK)	30 APRIL 1996	11 JANUARY 1994	NONE

2. Non-written disclosures (Rule 70.9)Kind of non-written disclosureDate of non-written disclosure
(day/month/year)Date of written disclosure
referring to non-written disclosure
(day/month/year)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US96/15596

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 10 and 20 are objected to as lacking clarity under PCT Article 6.

Claim 10 is a composition claim, as is claim 9, the claim from which claim 10 depends. However, claim 10 requires that sea water "is used ..." (emphasis added). Such language is clearly improper since this appears to be a method step for a composition.

Claim 20 is similarly defective because "use" of sea water is not permitted. Rather, the verb there should be changed to "present" or some other acceptable alternative.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US96/15596

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

~~Sheet 10~~

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(6): A61K 7/16, 7/20, 9/00, 9/12, 33/14, 33/40 and US Cl.: 424/43, 49, 53, 56, 400, 401, 405, 616, 680; 514/900, 901, 902, 945

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/15596

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61K 7/16, 7/20, 9/00, 9/12, 33/14, 33/40

US CL : Please See Extra Sheet.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/43, 49, 53, 56, 400, 401, 405, 616, 680; 514/900, 901, 902, 945

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3,976,223 A (JASS et al.) 24 August 1976, see column 5, line 33 to column 6, line 65; column 7, lines 19-21; Example A in columns 7-8.	1-20
Y	US 5,084,268 A (THALER) 28 January 1992, see column 5, lines 36-50; claims 1-15.	1-20
Y	US 5,104,644 A (DOUGLAS) 14 April 1992, see column 7, lines 3-7; column 8, lines 10-61.	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 04 DECEMBER 1996	Date of mailing of the international search report 17 JAN 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JOHN PAK <i>IW for</i> Telephone No. (703) 308-1235

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US96/15596

A. CLASSIFICATION OF SUBJECT MATTER:

US CL :

424/43, 49, 53, 56, 400, 401, 405, 616, 680; 514/900, 901, 902, 945

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61K 7/16, 7/20, 9/00, 9/12, 33/14, 33/40	A1	(11) International Publication Number: WO 97/10802 (43) International Publication Date: 27 March 1997 (27.03.97)
(21) International Application Number: PCT/US96/15596 (22) International Filing Date: 20 September 1996 (20.09.96) (30) Priority Data: 60/004,167 22 September 1995 (22.09.95) US (71) Applicant (for all designated States except US): PHYLOMED CORPORATION [US/US]; Suite One, 1850 N.W. 69th Avenue, Plantation, FL 33313 (US). (72) Inventor; and (75) Inventor/Applicant (for US only): MUNDSCHENK, David, D. [US/US]; 504 S.E. Second Avenue, Dania, FL 33004 (US). (74) Agents: GOLDMAN, Philip, M. et al.; Fredrikson & Byron, P.A., 1100 International Centre, 900 Second Avenue South, Minneapolis, MN 55402 (US).		(81) Designated States: CA, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: TOPICAL FORMULATIONS AND DELIVERY SYSTEMS (57) Abstract A system for delivering a chemical agent in the form of a foam, which in its preferred embodiment involves the use of an aerosol dispenser to deliver a formulation containing both an anionic surface active agent such as sodium lauryl sulfate as a delivery agent and a chemical agent such as either hydrogen peroxide as a disinfecting chemical agent or natural sea water.		

PATENT COOPERATION TREATY

01 Rec'd PCT/PTO 19 MAR 1998

09/043433

PCT

NOTICE INFORMING THE APPLICANT OF THE
COMMUNICATION OF THE INTERNATIONAL
APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:

GOLDMAN, Philip, M.
Fredrikson & Byron, P.A.
1100 International Centre
900 Second Avenue South
Minneapolis, MN 55402
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 27 March 1997 (27.03.97)		IMPORTANT NOTICE	
Applicant's or agent's file reference 15050.4.1 ✓			
International application No. PCT/US96/15596 ✓	International filing date (day/month/year) 20 September 1996 (20.09.96)	Priority date (day/month/year) 22 September 1995 (22.09.95) ✓	
Applicant PHYLOMED CORPORATION et al <i>boxed 4/1/97 dkw</i>			

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:

CA,EP,US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

None

The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 27 March 1997 (27.03.97) under No. WO 97/10802

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer J. Zahra Telephone No. (41-22) 730.91.11
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PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: PHILIP M. GOLDMAN
FREDRIKSON & BYRON, P.A.
1100 INTERNATIONAL CENTRE
900 SECOND AVENUE SOUTH
MINNEAPOLIS, MINNESOTA 55402

01 Rec'd PCT/PTO 19 MAR 1998
097043433 PCT

Received Intellectual
Property Department

JAN - 2 1998

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing
(day/month/year)

29 DEC 1997

Applicant's or agent's file reference

15050.4.1

IMPORTANT NOTIFICATION

International application No.

PCT/US96/15596

International filing date (day/month/year)

20 SEPTEMBER 1996

Priority Date (day/month/year)

22 SEPTEMBER 1995

Applicant

PHYLOMED CORPORATION

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Nothing to
Docket

Name and mailing address of the IPEA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

JOHN PAK

Telephone No. (703) 308-1235

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 15050.4.1	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US96/15596	International filing date (day/month/year) 20 SEPTEMBER 1996	Priority date (day/month/year) 22 SEPTEMBER 1995
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant PHYLOMED CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:
- I ☒ Basis of the report
 - II ☐ Priority
 - III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☒ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☒ Certain observations on the international application

Date of submission of the demand 22 APRIL 1997	Date of completion of this report 07 NOVEMBER 1997
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer JOHN PAK <i>Iw for</i>
Facsimile No. (703) 305-3230	Telephone No. (703) 308-1235

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US96/15596

I. Basis of the report

1. This report has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments):*

☒ the international application as originally filed.

☒ the description, pages 1-19 , as originally filed.

pages NONE , filed with the demand.

pages NONE , filed with the letter of _____.

pages _____ , filed with the letter of _____.

☒ the claims, Nos. 1-20 , as originally filed.

Nos. NONE , as amended under Article 19.

Nos. NONE , filed with the demand.

Nos. NONE , filed with the letter of _____.

Nos. _____ , filed with the letter of _____.

☒ the drawings, sheets/fig NONE , as originally filed.

sheets/fig NONE , filed with the demand.

sheets/fig NONE , filed with the letter of _____.

sheets/fig _____ , filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☒ the description, pages NONE .

☒ the claims, Nos. NONE .

☒ the drawings, sheets/fig NONE .

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US96/15596

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

Novelty (N)	Claims <u>9-10, 19-20</u>	YES
	Claims <u>1-8, 11-18</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-20</u>	NO
Industrial Applicability (IA)	Claims <u>1-20</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 9-10 and 19-20 meet the criteria set forth in PCT Article 33(2), because no single prior art reference can be found that explicitly discloses a delivery system comprising an aerosol dispenser containing purified sea water and an anionic surface active agent.

Claims 1-20 meet the criteria set forth in PCT Article 33(4), because the claimed invention finds industrial applicability in the delivery of active chemical agents.

Claims 1-8 and 11-18 lack novelty under PCT Article 33(2) as being anticipated by Jass et al.

Jass et al. explicitly disclose an aerosol dispenser that contains 3% hydrogen peroxide and 0.6% sodium lauryl sulfate (see Example A in columns 7-8, in particular, column 8, lines 48, 54 and 60-68). Consequently, instant claims 1-8 and 11-18 are anticipated by Jass et al.

Claims 1-20 lack an inventive step under PCT Article 33(3) as being obvious over Jass et al.

Jass et al. disclose the aerosol delivery of active agents (see from column 1, line 66 to column 2, line 6; and column 5, line 23 to column 6, line 65). Hydrogen peroxide with surfactant such as sodium lauryl sulfate is disclosed (column 5, line 45; column 6, lines 57-58; Example A at columns 7-8). Carrier system containing sodium lauryl sulfate is disclosed (Table I at columns 7-8).

The only difference between the claimed invention and Jass et al. is that Jass et al. do not expressly disclose the use of purified sea water as the "chemical agent." However, given the status of purified sea water as a well known therapeutic agent (see applicant's admission in description page 3, lines 7-10), its incorporation into Jass' delivery system for myriad active agents would have been well within the skill of the ordinary skilled artisan.

Therefore, the claimed invention, as a whole, would have been obvious to the routinier in the art, and claims 1-20 lack an inventive step under PCT Article 33(3).

_____ NEW CITATIONS _____

NONE

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US96/15596

VI. Certain documents cited**1. Certain published documents (Rule 70.10)**

<u>Application No. Patent No.</u>	<u>Publication Date (day/month/year)</u>	<u>Filing Date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
US, A, 5,512,278 (MUNDSCHEK)	30 APRIL 1996	11 JANUARY 1994	NONE

2. Non-written disclosures (Rule 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure (day/month/year)</u>	<u>Date of written disclosure referring to non-written disclosure (day/month/year)</u>
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VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 10 and 20 are objected to as lacking clarity under PCT Article 6.

Claim 10 is a composition claim, as is claim 9, the claim from which claim 10 depends. However, claim 10 requires that sea water "is used ..." (emphasis added). Such language is clearly improper since this appears to be a method step for a composition.

Claim 20 is similarly defective because "use" of sea water is not permitted. Rather, the verb there should be changed to "present" or some other acceptable alternative.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US96/15596

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(6): A61K 7/16, 7/20, 9/00, 9/12, 33/14, 33/40 and US Cl.: 424/43, 49, 53, 56, 400, 401, 405, 616, 680; 514/900, 901, 902, 945

PATENT COOPERATION TREATY

01 Rec'd PCT/PTO 19 MAR 1998
09/043433

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To: PHILIP M. GOLDMAN
FREDRIKSON & BYRON, P.A.
1100 INTERNATIONAL CENTRE
900 SECOND AVENUE SOUTH
MINNEAPOLIS, MINNESOTA 55402

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 15050.4.1	Date of Mailing (day/month/year) 17 JAN 1997
International application No. PCT/US96/15596	International filing date (day/month/year) 20 SEPTEMBER 1996
Applicant PHYLOMED CORPORATION	

17 April 1997 file PCT search in US
 17 March 1997 amendments
 -1/24/97 CKW

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.
Filing of amendments and statement under Article 19:
 The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):
 When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.
 Where? Directly to the International Bureau of WIPO
 34, chemin des Colombettes
 1211 Geneva 20, Switzerland
 Facsimile No.: (41-22) 740.14.35
 For more detailed instructions, see the notes on the accompanying sheet.
2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
 - ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
 - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.
4. Further action(s): The applicant is reminded of the following:
 Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 bis 1 and 90 bis 3, respectively, before the completion of the technical preparations for international publication.
 Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).
 Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JOHN PAK <i>IW for</i> Telephone No. (703) 308-1235
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 15050.4.1	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US96/15596	International filing date (<i>day/month/year</i>) 20 SEPTEMBER 1996	(Earliest) Priority Date (<i>day/month/year</i>) 22 SEPTEMBER 1995
Applicant PHYLOMED CORPORATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (See Box I).
2. ☐ Unity of invention is lacking (See Box II).
3. ☐ The international application contains disclosure of a nucleotide and/or amino acid sequence listing and the international search was carried out on the basis of the sequence listing

☐ filed with the international application.
☐ furnished by the applicant separately from the international application,

☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.

☐ transcribed by this Authority.
4. With regard to the title, ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:
5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. The figure of the drawings to be published with the abstract is:
 Figure No. _____

☐ as suggested by the applicant.
☐ because the applicant failed to suggest a figure.
☐ because this figure better characterizes the invention.

☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/15596**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :A61K 7/16, 7/20, 9/00, 9/12, 33/14, 33/40

US CL :Please See Extra Sheet.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/43, 49, 53, 56, 400, 401, 405, 616, 680; 514/900, 901, 902, 945

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3,976,223 A (JASS et al.) 24 August 1976, see column 5, line 33 to column 6, line 65; column 7, lines 19-21; Example A in columns 7-8.	1-20
Y	US 5,084,268 A (THALER) 28 January 1992, see column 5, lines 36-50; claims 1-15.	1-20
Y	US 5,104,644 A (DOUGLAS) 14 April 1992, see column 7, lines 3-7; column 8, lines 10-61.	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

04 DECEMBER 1996

Date of mailing of the international search report

17 JAN 1997

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

JOHN PAK

Telephone No. (703) 308-1235

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US96/15596

A. CLASSIFICATION OF SUBJECT MATTER:

US CL :

424/43, 49, 53, 56, 400, 401, 405, 616, 680; 514/900, 901, 902, 945

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty and of the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended ?

The claims only.

The description and the drawings may only be amended during international preliminary examination under Chapter II.

When ? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

What documents must/may accompany the amendments ?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confounded with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.